

REMARKS

Applicant's attorney wishes to thank Examiner Ryckman for the careful consideration given this case and the courteous interview of March 13, 2008. During the interview Applicant's representatives pointed to numerous differences between the device of the pending claims and the cited prior art. The Examiner asserted that such differences fall within the scope of the broadest reasonable interpretation of the cited prior art. Claims 1-3, 5 and 7-16 are pending in this application. No claim amendments are presented at this time.

As discussed during the interview and as the Examiner is aware, the pending case is a continuation-in-part of U.S. Patent Application No. 10/086,318 filed March 3, 2002 now U.S. Patent No. 6,743,241 which includes issued claims that are substantially similar to the pending claims in this case.

35 U.S.C. § 102(b)

Claims 1-3, 5, 7-9 and 14-16 are again rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,586,986 to Hinchliffe (hereinafter "Hinchliffe"). The Examiner alleges that the device of Hinchliffe meets all of the limitations presented in the identified claims. Applicant respectfully disagrees.

First, the Examiner asserts that the needles of Hinchliffe are curved and thus "comprised of many angles." Therefore, the Examiner alleges that the broadest reasonable interpretation of the term "curved" would encompass the claimed angled needles despite the clear physical differences exhibited by the angled needles provided in Applicant's figures and described in Applicant's specification. The Examiner is reminded that "the claim as a whole must be considered" (MPEP 2141.02), and in interpreting the term "angled" as described above and asserting that the curved needles of Hinchliffe and the angled needles of the pending claims

are equivalent, the Examiner is failing to consider the pending claims as a whole. In particular, in the Response and Amendment filed September 17, 2007 Applicants clarified that the angled needles of independent claims 1 and 16 are “capable of traversing at least one tissue layer in an orientation that is generally perpendicular to the tissue layer and generally parallel to the cannula.” During the interview, the Examiner stated that she understood that curved needles, such as those described and pictured in Hinchliffe would necessarily traverse tissue layers in an arc. As such, it would be impossible for the needles of Hinchliffe to traverse at least one tissue layer in the manner recited in independent claims 1 and 16.

Additionally, in the outstanding Office Action, the Examiner appears to assert that the *device* of Hinchliffe is capable of piercing the tissue layers in an orientation that is generally perpendicular to the tissue layer and parallel to the cannula (*see* Office Action, page 3). Such argumentation is inconsistent with the terminology set forth in the pending claims because independent claims 1 and 16 clearly recite that the needles are “capable of traversing at least one tissue layer in an orientation that is generally perpendicular to the tissue layer and generally parallel to the cannula.” As described in Applicant’s specification, a tissue layer is traversed following penetration of the tissue layer by the needles (*see* para [0036]). The needles of Hinchliffe are not capable of traversing a tissue layer in such a manner, because needles having a shape as described and depicted in Hinchliffe necessarily traverse tissue in an arc as conceded by the Examiner. Accordingly, Hinchliffe fails to describe angled needles as recited in the pending claims and, therefore, fails to anticipate Applicant’s claimed device.

Second, Hinchliffe fails to describe a “first operative position” in which the “needle holder arms *extend* in opposed directions from the distal end of said cannula” (emphasis added) as recited in independent claim 1. The Examiner alleges that FIG. 4 of Hinchliffe shows

needle holder arms in the “first operative position” of independent claims 1 and 16. Here again, the Examiner fails to consider the claimed invention as a whole. Specifically, the needle holder arms of FIG. 4 are enclosed within the cannula and not extended in opposed directions from the cannula as claimed. In fact, Hinchliffe characterizes the needle holder arms of FIG. 4 as being “retracted” (col. 5, lines 9-11) which would be construed as meaning not extended. Moreover, the term “extended” is clearly defined in Applicant’s specification where the operative configuration described in claims 1 and 16 are said to “*extend* outwardly” and “spread out and *extend* away” from the cannula (*see, e.g.,* paras [0010] and [0034]). To further contrast Applicant’s use of the term “extend,” the examiner’s attention is called to Applicant’s FIG. 4 which shows Applicant’s extended configuration as required by independent claim 1 in comparison to Hinchliffe’s FIG. 4. Hinchliffe clearly fails to describe a “first operative configuration” in which the needle holder arms are extended as recited in independent claims 1 and 16, and hence fails to anticipate Applicant’s pending claims.

For at least the reasons provided above, Hinchliffe fails to describe each and every element of independent claims 1 and 16 and, therefore, fails to anticipate the indicated claims. Accordingly, the Examiner’s rejection under 35 U.S.C. § 102(b) should be withdrawn. Reconsideration is respectfully requested.

With regard to Claim 2, the Examiner appears to assert that the additional configurations recited in claim 2 are anticipated by Hinchliffe’s FIG. 4 and FIG. 6 (Office Action pg. 3). However, in rejecting independent claim 1, the Examiner points to FIG. 4 as characterizing the first operative configuration and FIG. 6 as characterizing the second operative configuration. It is unclear how FIG. 4 and FIG. 6 can each depict more than one configuration.

Therefore, Hinchliffe fails anticipate the operative configurations of claim 1 and the configurations of claim 2, and the Examiner's rejection of claim 2 should be withdrawn.

With regard to claim 7, the Examiner contends that FIG. 4 of Hinchliffe illustrates the first operative configuration. Therefore, the Examiner appears to allege that the configuration depicted in FIG. 4 shows needle holder arms that "extend across said puncture site" as recited in claim 7. Applicant asserts that needle holder arms in the configuration depicted in FIG. 4, are clearly enclosed within the cannula and not extended across the puncture site. Accordingly, Hinchliffe fails to anticipate claim 7.

With regard to claim 13, the Examiner appears to allege that the "teeth 40" at the end of the "elongated rod 36" of Hinchliffe anticipate the "tapered mount" recited in claim 13. The "tapered mount" of claim 13 is clearly defined in Applicant's specification as being useful for gathering tissue (*see* para [0010] and [0036]). In contrast, the teeth of Hinchliffe mesh with the teeth of the carrier arms (*see* col. 4, lines 60-63), and the teeth of Hinchliffe are inoperative to facilitate gathering of tissue as described in Applicant's specification because if tissue were gathered using the mechanism of Hinchliffe, such tissue would surely be destroyed. Clearly, the teeth of Hinchliffe do not anticipate the "tapered mount" of claim 13, and the Examiner's rejection should be withdrawn.

35 U.S.C. § 103

Claims 10-12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hinchliffe in view of U.S. Patent No. 5,860,991 to Klein et al. (hereinafter "Klein").

First and foremost, the combination of Hinchliffe and Klein fails to provide a needle trap mechanism operative to draw the needles into the lumen of the cannula as recited in independent claim 1, and therefore, the combination of Hinchliffe and Klein fails to obviate

claims 10-12. Hinchliffe fails to provide sufficient space within the cannula to store the needles. Therefore, even if the needle trap mechanism of Klein including a sheath (S of Klein FIGs 7-12) were combined with the device of Hinchliffe, the needles of Hinchliffe would extend outside of the cannula as pictured and could not be covered by the sheath of Klein. Moreover, neither Hinchliffe nor Klein provides a mechanism that could be modified to function to draw needles into the lumen of the cannula as required by the pending claims. Accordingly, the combination of Hinchliffe and Klein fail to render independent claim 1 and thus claims 10-12 obvious. Withdrawal of the Examiner's rejection is respectfully requested.

Additionally, as described hereinabove, Hinchliffe fails to describe or fairly suggest a device having needles that are capable of traversing "at least one tissue layer in an orientation that is generally perpendicular to the tissue layer and generally parallel to the cannula" as described in independent Claim 1. Klein fails to cure these deficiencies. Specifically, the needles of Klein are curved. In fact, because there is no mechanical means for drawing the needles of Klein through the tissue and toward the needle trap mechanism, the needles of Klein necessarily must be curved such that they can traverse the tissue in an arc and be retained in the needle trap mechanism of Klein. Replacing the curved needles described and depicted in Klein with angled needles as recited in the pending claims would render the device of Klein inoperable because such angled needles would never reach the needle trap mechanism of Klein.

During the interview, the Examiner asserted that a portion of the needles of Klein located at the base of the needle, the "needle shank 26" as described in Klein, are generally perpendicular to the cannula of Klein when the needles traverse the tissue. Here again, the Examiner is failing to consider the pending claims as a whole. Specifically, Applicant's

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independent claim 1 recites: “*angled needles are capable of traversing at least one tissue layer* in an orientation that is generally perpendicular to the tissue layer and generally parallel to the cannula.” Even if the needles shanks of Klein are generally parallel to the cannula when the needles traverse tissue, the needle of Klein do not traverse at least one tissue layer in a generally perpendicular manor. Thus, Klein fails to teach or fairly suggest angled needles and, moreover, fails to render Applicant’s claimed angled needles obvious.


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CONCLUSION

In view of the amendments and remarks presented hereinabove, Applicant submits that the pending claims are in condition for allowance and respectfully request that they be passed to issue. Should the Examiner have any questions or comments, or need any additional information from Applicant's attorney, she is invited to contact the undersigned at her convenience.

In the event that any additional fees are required with this submission, the Commissioner is hereby authorized to charge or credit such fees to Deposit Account No. 50-0436.

Respectfully Submitted,

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